

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

03-0116 (US01)

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Application Number

10/695,151

Filed

October 27, 2003

on March 11, 2008

Signature

Nancy Rushton

First Named Inventor

Stephen C. Porter

Typed or printed

Nancy Rushton

Name

Art Unit

3731

Examiner

Elizabeth Houston

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
☐ assignee of record of the entire interest.
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
 (Form PTO/SB/96)

☒ attorney or agent of record.Registration number 37,104☐ attorney or agent acting under 37 CFR 1.34.

Registration number _____

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Telephone number

March 11, 2008

Date

☒ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:)	Group Art Unit: 3731
Stephen Porter)	Confirmation No.: 6462
Serial No.: 10/695,151)	Examiner: Elizabeth Houston
Filed: October 27, 2003)	
For: VASO-OCCLUSIVE DEVICES WITH)	
IN-SITU STIFFENING ELEMENTS)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully requests a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1-16, 20-30, 32-38 and 40-42 remain pending in this application. Claims 1-5, 10, 12, 15, 16, 20, 30, 32, 33 and 40 are provisionally rejected under nonstatutory double patenting grounds over U.S. Patent Publication No. 2004/0098028 ("Martinez"). Claims 1, 2, 4-6, 7, 10, 11, 14-16, 20, 21, 30 and 40 stand rejected under 35 U.S.C. §102 (e) as allegedly being anticipated over Martinez. Claims 1-8, 14, 15, 20, 21, 27-30, 32-35 and 40-42 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent Publication No. 2004/0098023 ("Lee") in view of U.S. Patent No. 7,066,904 ("Rosenthal"). Claims 9-13, 22-26, 28, 29, 36 and 37 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lee in view of Rosenthal, and in further view of U.S. Patent Publication No. 2001/0046518 ("Sawhney"). Applicant respectfully traverses these rejections.

Nonstatutory Double-Patenting rejection

The double patenting rejection is improper since the assignee of this application (Boston Scientific Scimed, Inc. formerly Scimed Life Systems, Inc.) is not the assignee of Martinez, and as such, Applicant requests withdrawal of this rejection.

Claim rejections under 35 U.S.C. §102 (e)

Independent claims 1, 30, and 40 each recite an active element (claims 1 and 40) or hydrogel member (claim 30) carried entirely within the lumen defined by a vaso-occlusive member, the active element or hydrogel contracts to a deployed configuration that causes the occlusive member to substantially retain its shape (claims 1 and 30) or to stiffen (claim 40) when deployed in a body cavity (claims 1 and 40) or vasculature (claim 30). Martinez does not disclose each and every element required by these claims, since no such active element that contracts to cause the occlusive member to retain its shape is disclosed expressly or inherently in Martinez.

The Examiner states that it is somehow inherent that the hydrogel of Martinez *"will lose some of its moisture to the environment and will contract (even if only at microscopic level)"* within time, but that *"the hydrogel will still be expanded enough to hold cause the coil to retain its shape but will be contracted radially"* (page 4 of final office action). In contrast, Martinez expressly discloses that the active element is configured to expand and protrude through the gaps of the outer element upon exposure to the environment, to minimize friction with a delivery catheter, enhance pushability, trackability and increase flexibility of the device when deployed through the delivery catheter (Paragraphs 12 and 13).

Inherency relates to existing parts or consequences as a natural result of an explicit disclosure (Schering, 339 F. 3d at 1379). Inherency, however, may not be established by probabilities or possibilities (MPEP 2163.07). Applicant believes the Examiner has erred in finding that Martinez inherently discloses an active element that contracts, since it explicitly discloses the exact opposite, and it is not a natural result that the active element contracts when, in fact, it expands upon exposure to the environment. Expansion of the active element is essential to the disclosure of Martinez; subsequent contraction is merely speculation of the Examiner.

Moreover, claims 1, 30, and 40 also require that the contraction of the active element causes the occlusive member to substantially retain its shape. The contraction of the active element compresses the occlusive member to stiffen and stabilize the shape of the occlusive member, which is obtained even during the delivery of the occlusive member by being reshaped and stabilized in-situ. The contraction of the

active element is what actually causes the occlusive member to substantially retain its shape, as disclosed in the specification. Martinez does not disclose, expressly or inherently, this requirement of the claims; instead, the active element expansion (not contraction) of Martinez is said to minimize friction and enhance pushability and flexibility of the device in relationship with the delivery catheter.

For at least these reasons, Applicant respectfully submits that independent claims 1, 30, and 40, along with claims 2, 4-6, 7, 10, 11, 14-16, 20 and 21, which depend directly or indirectly from claim 1, are not anticipated by Martinez, and as such, requests withdrawal of the §102 rejection of these claims.

Claim rejections under 35 U.S.C. §103

Claims 1-8, 14, 15, 20, 21, 27-30, 32-35 and 40-42 are rejected as allegedly being obvious over Lee in view of Rosenthal. Lee discloses a vaso-occlusive device comprising a core member and fibrous structure coupled to the core member, wherein a bioactive material may be used to coat, or is otherwise included in, the composition of the core member. Rosenthal discloses a balloon catheter comprising a hydrogel coating on its outer surface; the hydrogel carries a drug that is released from the hydrogel in a body when the hydrogel is exposed to a triggering agent, which causes the hydrogel to contract, and the drug to be squeezed out of the contracted hydrogel.

Lee's element (14) is a fibrous structure surrounding the core member (12), composed by randomly oriented fibers that merely clings in some fashion to the core member; it does not take on or retain any particular shape when deployed in the body. Thus, even if a person skill in the art would combine Lee in view of Rosenthal, the resulting device would be an occlusion device with fibrous elements, the device also having an expandable balloon with a hydrogel coating that carries a drug that is released when the hydrogel contracts and the drug is squeezed out. Such combination will not result in an active element carried entirely within the lumen defined by a vaso-occlusive member, where the active element contracts to a deployed configuration that causes the occlusive member to substantially retain its shape when deployed, as recited in claims 1, 30 and 40.

For a combination of prior art references to render a claim obvious, the resulting prior art device or method must include all of the limitations of that claim (MPEP §2143). There is nothing in Lee in view of Rosenthal that disclose or suggest that their combination will result in an occlusive member having an active element configured to contract, causing the occlusive member to retain its shape when deployed in a body.

Dependent claims 9-13, 22-26, 28, 29, 36 and 37 are rejected over Lee in view of Rosenthal and in further view of Sawhney. In particular, Sawhney discloses methods for hydrating (expanding) hydrogel in situ, which releases therapeutic agents to a body to promote sealing or augmentation of tissue or vessels (Paragraphs 22, 26, 104). As indicated above, the combination of Lee and Rosenthal will not result in an occlusive member having an active element configured to contract, causing the occlusive member to retain its shape when deployed in a body, and Sawhney does not provide the missing limitations required in claims 1, 30 and 40.

For at least these reasons, independent claims 1, 30 and 40 are believed patentable over the combination of Lee and Rosenthal. Dependent claims 3-2-15, 20-29, 32-38 and 41-42 are also believed patentable over such combination, including the addition of Sawhney, for at least the same reasons.

CONCLUSION

For the reasons set forth above, Applicant respectfully submits that currently pending claims are patentable over the cited prior art. A notice of allowance is respectfully requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: 3-11-08

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